

14 April 2020

Open letter to European Member States on the need for a continued access to plasma-derived medicinal products and for strengthening the collection of blood and plasma

Dear Minister of Health,

On behalf of the Platform of Plasma Protein Users, a coalition of organisations representing patients with rare plasma-related disorders whose health and lives rely on a stable and diverse supply of plasma-derived medicinal products, we are writing to European policy makers in Member States to call on governments to ensure that collection of blood and plasma can continue to be done with the required safety measures for both donors and the centres' staff so that patients can continue having a sustained and optimal access to plasma-derived medicinal products.

In these trying times for governments having to manage a pandemic of such unprecedented impact in healthcare systems, economy and society, we would like to draw your attention to the needs of the patients we represent. Our patients rely on a sustained and optimal access to plasma-derived medicinal products to cope with their rare disorders adequately. This sustained access requires a sufficient supply of blood and plasma for the development of medicinal products.

Plasma for the manufacture of medicinal products and plasma for fractionation has recently been defined by the European Centre for Disease Prevention and Control (ECDC) as "*an essential substance of human origin*" (SoHO) and considered that "*maintaining a safe, sufficient and accessible supply of critical and essential SoHO during a pandemic is of vital interest to public health*¹". The ECDC has reflected that the current COVID-19 pandemic may pose a challenge in the adequate supply of SoHO including plasma for the manufacture of medicinal products and has listed mitigation measures "*to make every effort to ensure a continued supply of safe, high-quality, life-saving products and services at the level demanded by the healthcare community*²".

The different containment and social distancing measures could jeopardize appropriate and sufficient collection of blood and plasma in all EU member states. In times where social distancing and reduction of movements to avoid contagions is becoming the norm, we urge public health authorities to develop and/or support communication campaigns to raise awareness about the importance of

¹ Coronavirus disease (COVID-19) and supply of substances of human origin in the EU/EEA. ECDC. 20 March 2020. Accessed on April 1st 2020: <https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-supply-substances-human-origin.pdf>

² Ibid

donating **both** blood and plasma whilst also communicating on the measures to guarantee donor safety.

The current COVID-19 outbreak and the drop in blood and plasma donation frequency are a tragic example that underlines one of PLUS' key messages: the main safety issue for patients relying on plasma-derived medicinal products today is their supply. From our perspective as patients, our safety depends on two main aspects: more balanced plasma collection between the different world regions to optimize the global supply of plasma and reduce dependency on one region only and in the free circulation of plasma-derived medicinal products between world countries to ensure that patients whose lives depend on them can access them.

Another aspect to avoid any potential tension in the availability of plasma-derived medicinal products in the coming months, is the development of a contingency plan for the different plasma-derived medicinal products in collaboration with the different relevant stakeholders including relevant patient organisations. These plans should be fact-based and include concrete measures to ensure that, in terms of shortages, the demand would be managed in a way that would be allocated to the different indications depending on their prioritisation, so as to ensure that patient populations can continue to access according to their needs.

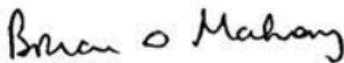
PLUS organisations remain at your disposal should you or your staff wish to discuss any of the measures mentioned further and to support your Ministry's efforts in ensuring that patients continue having a sustained and continued access to life-saving plasma-derived medicinal products.

We thank you very much in advance for your consideration and look forward to hearing from you,

Yours faithfully,



Frank Willersinn, M.D.,
President Alpha-1 Plus



Brian O'Mahony
EHC Medical and Scientific Advisory Group



Johan Prévot
IPOPI Executive Director

About PLUS: PLUS is a coalition of organisations which represent the views of over 110,000 patients in Europe who are regular users of plasma or plasma derived products. We represent the views of the European Haemophilia Consortium (EHC), the World Federation of Hemophilia (WFH), the International Patients Organisation for Primary Immune Deficiencies (IPOPI), Alpha-1 Plus, the GBS/CIDP Foundation, Hereditary Angio-Odema International (HAEI) and the ITP Support Association.